GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:336
ANSWERED ON:03.02.2017
Increase in Hepatitis Cases
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether cases of hepatitis infections are on the rise in the country, if so, the details thereof and the reasons therefor;

(b) the number of cases of various types of hepatitis infections reported during each of the last three years and the current year, type and State/UT-wise;

(c) the measures taken/proposed to be taken by the Government for prevention and control of hepatitis along with the funds allocated and utilised for the purpose during the said period, State/UT-wise;

(d) whether the Government has recently given licence to manufacture drug for hepatitis, if so, the details thereof; and

(e) the steps taken/proposed to be taken by the Government to eliminate hepatitis including immunization and ensure the quality and safety of the anti-hepatitis drugs?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SMT. ANUPRIYA PATEL)
(a) to (d): The number of cases due to Viral Hepatitis as reported by the States/UTs to Central Bureau of Health Intelligence (CBHI) in the last three years is given at Annexure. Separate figures for various types of Hepatitis are not collected at present.

The main cause of Hepatitis A & E is consumption of contaminated water and providing provision for safe drinking water is the main strategy to control it. Rural water supply is a State subject. Government of India supplements the efforts of the States by providing technical and financial assistance under the centrally sponsored National Rural Drinking Water Programme (NRDWP) for providing safe and adequate drinking water supply facilities in rural areas of the country.

Hepatitis B vaccination is included under the Universal Immunization Programme (UIP) of Government of India. Government is using auto-disabled (AD) syringes for all vaccinations under the UIP in all States. There is no vaccine available for Hepatitis C.

Screening of blood reduces the risk of transmission of Hepatitis B and C by blood transfusion. Therefore, blood banks mandatorily screen for Hepatitis B & C as per Drugs & Cosmetics Act 1940 and Rules thereunder.

The Government of India has recently instituted a "National Viral hepatitis Surveillance Programme" under the 12th five year plan (2012-17) with an estimated budget of Rs. 30 crore. The initial funds have been released to National Centre for Disease Control (NCDC) in this current financial year and the surveillance activities have been initiated.

NCDC also provides technical guidance to State Governments, laboratory support for outbreak investigations and etiological diagnosis besides conducting regular training courses for development of trained manpower. Funds are released to States/UTs under Integrated Disease Surveillance Programme (IDSP) to strengthen surveillance and to detect and respond to outbreaks of epidemic-prone diseases.

Many antiviral drugs like Lamivudine, Adefovir Dipivoxil, Entecavir, Telbivudine, Tenofovir etc., for treatment of Hepatitis B and Sofosbuvir, FDC of Ledipasvir and Sofosbuvir 400 mg, Daclatasvir etc., for the treatment of Hepatitis C have been approved in the country.

Central Drugs Standard Control Organization (CDSCO) has granted import and marketing permission on 13th January, 2015 for Sofosubuvir 400 mg tablet (brand name Sovaldi) manufactured by M/s Gilead Science Ltd. for treatment of chronic Hepatitis C in adults.

Subsequently, since March 2015, CDSCO has also granted permission to manufacture and market Sofosubuvir 400 mg tablet to a

few Indian manufacturers.

(e): Drugs including anti-hepatitis are regulated under the provisions of Drugs and Cosmetics Act, 1940 and Rules 1945 made thereunder.

1. Under the Act and Rules, the regulatory control over the drugs imported into the country is exercised by the Central Government through the Central Drugs Standard Control Organization (CDSCO). For import and marketing of drugs, the overseas manufacturing premises and the drugs are required to be registered and license is required to be obtained from CDSCO.

2. New drugs are approved in accordance with provision of the Drugs and Cosmetics Act, 1940 and Rules, 1945 made thereunder after being satisfied that the drug permitted to be imported/ manufactured shall be effective and safe for use in the country

3. Detailed requirements and guidelines for manufacture/import of new drugs in the country are specified under Rule 122A, 122B, 122D, 122E and Schedule Y of Drugs and Cosmetics Act, 1940 and Rules, 1945.

4. However, for manufacture/Import and marketing of any new drug, prior permission from CDSCO is required to be obtained.

5. The manufacture, sale and distribution of drug is regulated under the said Act & Rules by the State Drugs Control Authorities appointed by the State Governments. The regulatory control over the manufacture and sale of the drugs is exercised through a system of licensing and inspection.